

## **PSJ1 Exh 2**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

*This document relates to:*

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO  
DEFENDANT HBC'S MOTION FOR SUMMARY JUDGMENT**

July 31, 2019

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Plaintiffs respectfully submit this memorandum of law in opposition to Defendant HBC Service Company's ("HBC") motion for summary judgment (ECF No. 1912).<sup>1</sup>

## **I. STATEMENT OF UNDISPUTED MATERIAL FACTS**

In 2009, Giant Eagle made a business decision to begin acting as a distributor of controlled substances.<sup>2</sup> Giant Eagle chose to put the distributor's license in the name of the business entity that operated the distribution warehouse, HBC.<sup>3</sup> During the next five years, HBC acted as a major distributor of controlled substances, shipping over 23 million dosage units of hydrocodone combination products ("HCPs") into Cuyahoga and Summit Counties.<sup>4</sup> Giant Eagle estimates that by using HBC as a distributor as opposed to a third-party, it saved at least \$20 million per year.<sup>5</sup> Giant Eagle and HBC did not have the experience or personnel necessary to develop – and failed to implement – an appropriate compliance department that could monitor the large quantities of HCPs flowing through HBC into Giant Eagle pharmacies. As detailed below, Plaintiffs' evidence establishes that HBC did not hire experienced compliance officers, did not design a system to identify suspicious orders of controlled substances, did not operate a system to identify suspicious orders of controlled substances, did not stop a single order of HCPs (even though its highly flawed monitoring system still flagged numerous suspicious orders), and did not report a single suspicious order to the DEA.<sup>6</sup>

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<sup>1</sup> References to "HBC Mem. \_" are to pages of the Brief in Support of HBC Service Company's Motion for Summary Judgment. Unless otherwise indicated, references to Giant Eagle, Inc. ("Giant Eagle") include HBC.

<sup>2</sup> PSJ13-HBC Opp Exh 1, HBC Service Company's Supplemental Answers to Plaintiffs' First Set of Interrogatories to HBC Service Company, Supp. Resp. to Interrog. No. 23, p. 42 (HBC began distributing opioids in November 2009).

<sup>3</sup> Randy Heiser Dep. (Feb. 19, 2019), Dkt. # 1962-27 at 16:13-17:1.

<sup>4</sup> PSJ13-HBC Opp Exh 2, HBC\_MDL00189212; PSJ13-HBC Opp Exh 3, HBC\_MDL00189213.

<sup>5</sup> Gregory Carlson Dep. (Jan. 8, 2109), Dkt. # 1959-18 at 33:7-14 (testifying Giant Eagle saved over \$20 million per year through HBC distribution); *see also* Heiser Dep., Dkt. # 1962-27 at 13:21-15:4.

<sup>6</sup> *See* James Tsipakis Dep. (Jan. 13, 2018), Dkt. # 1971-12 at 213:8-11, 255:24-256:23; PSJ13-HBC Opp Exh 4, HBC\_MDL00135022; PSJ13-HBC Opp Exh 5, HBC\_MDL00028498.

**A. THE UNDISPUTED EVIDENCE SHOWS THAT HBC DID NOT COMPLY WITH THE STANDARD OF CARE APPLICABLE TO DISTRIBUTORS OF CONTROLLED SUBSTANCES**

Contrary to HBC's assertion that it complied with all requirements of the Controlled Substances Act ("CSA"), the undisputed evidence establishes that Giant Eagle and HBC had problems with diversion and failed to detect and deter diversion at their respective corporate, warehouse, and pharmacy levels.<sup>7</sup>

*1. HBC Did Not Design and Operate a System to Detect Suspicious Orders of Opioids*

- (a) HBC did not create any written Suspicious Order Monitoring policies until August 2014.

HBC began distributing opioids in November 2009 and stopped in October 2014.<sup>8</sup> HBC's earliest written compliance policy is dated August 1, 2014.<sup>9</sup> HBC thus operated as a distributor of controlled substances without a written suspicious order monitoring ("SOM") policy for nearly five years, for all but two months in which it distributed controlled substances.<sup>10</sup>

- (b) HBC's threshold monitoring system was deeply flawed.

From November 2009 to October 2013, HBC distributed controlled substances to its approximately 200 pharmacies with no system to review their order size or frequency.<sup>11</sup> Beginning on October 15, 2013, HBC began monitoring its stores' orders against a threshold based on the average of all of its store's orders for that drug multiplied by three.<sup>12</sup> Even HBC's Rule 30(b)(6) representative,

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<sup>7</sup> For HBC's breakdown of its closed system into these parts, *see* Tsipakis Dep., Dkt. # 1971-12 at 281:23-282:3.

<sup>8</sup> *See* PSJ13-HBC Opp Exh 6, HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests, Dec. 29, 2018, Request 2, pp. 8-9.

<sup>9</sup> *See* PSJ13-HBC Opp Exh 7, HBC\_MDL00133445 (HBC Service Company Inventory Controls Policy (Version 1), Aug. 1, 2014).

<sup>10</sup> *Id.*

<sup>11</sup> HBC's threshold reports are Excel spreadsheets titled "Daily\_HBC\_Controls," the first being PSJ13-HBC Opposition Exhibit 8, HBC\_MDL00002249, Oct. 15, 2013. *See also* Tsipakis Dep., Dkt. # 1971-12 at 129:25-130:3 ("[thresholds began] sometime in 2013"); *id.* at 154:1-2 ("Q. How many pharmacies in the entire chain? A. Over 200.").

<sup>12</sup> Tsipakis Dep., Dkt. # 1971-12 at 118:2-12.

James Tsipakis, admitted that the system was flawed because smaller customers' larger-than-normal orders might not reach 300% of the *average* store's order.<sup>13</sup>

(c) HBC did not properly investigate flagged orders of opioids.

Moreover, the record does not support HCP's argument that even those suspicious orders that were flagged were investigated. Rather, HBC did not keep written records of investigating orders exceeding its thresholds and did not have a system in place that would ensure that each store was reviewed.<sup>14</sup>

(d) HBC failed to stop any suspicious orders of HCPs.

Despite shipping **over 23,000,000** units of HCPs into the Plaintiffs' jurisdictions over a five-year period, HBC **failed to stop a single shipment** of a suspicious order.<sup>15</sup> After HBC stopped shipping controlled substances, its parent company, Giant Eagle, had the opportunity (for its new distribution center) to utilize a third-party system to stop orders over its threshold for shipping. Giant Eagle's Senior Pharmacy Director, Adam Zakin, declined to do so, however, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."<sup>16</sup>

(e) HBC failed to report any suspicious orders of HCPs.

Despite countless orders over its established thresholds,<sup>17</sup> HBC failed to identify and report to the DEA even a single shipment of a suspicious order for HCP from any of its 200 customers.<sup>18</sup>

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<sup>13</sup> *Id.* at 306:3-14.

<sup>14</sup> *See* Robert Chunderlik Dep. (Jan. 16, 2019), Dkt. # 1959-24 at 134:8-13, 217:21-218:19, 305:4-14; Carlson Dep., Dkt. # 1959-18 at 208:1-11; Tsipakis Dep., Dkt. # 1971-12 at 160:16-161:4.

<sup>15</sup> *See* Tsipakis Dep., Dkt. # 1971-12 at 213:8-10, 255:24-256:23; PSJ13-HBC Opp Exh 4; PSJ13-HBC Opp Exh 5.

<sup>16</sup> *See* PSJ13-HBC Opp Exh 5.

<sup>17</sup> *See, e.g.*, PSJ13-HBC Opp Exh 5; PSJ13-HBC Opp Exh 9, HBC\_MDL00008498.

<sup>18</sup> In fact, only one suspicious order was identified during HBC's period of distributing HCPs. *See* PSJ13-HBC Opp Exh 6, at Req. 3, p. 11 ("On December 5, 2013, HBC identified a suspicious order for buprenorphine 8mg SL tab . . . and reported the order to the DEA on the same day.").

2. *HBC's Compliance Department Was Unqualified, and HBC Failed to Keep Any Records of Investigations or Other Compliance Efforts*

HBC provided no education regarding how to identify suspicious orders or other program to address diversion to its employees.<sup>19</sup> HBC did not keep written records of investigating orders exceeding its thresholds.<sup>20</sup> Without training or document diligence, HBC failed to maintain a system sufficient to prevent diversion and handle suspicious orders. The DEA has specifically acknowledged that “all records of the investigation should be retained in an appropriate location” as part of “a compliant suspicious order monitoring program.”<sup>21</sup>

3. *Giant Eagle's Pharmacy Staff Were Caught Diverting Opioids*

HBC deponents admitted that Giant Eagle pharmacy staff have diverted opioids, amounting to tens of thousands of units.<sup>22</sup> In addition, the State of Ohio Board of Pharmacies found that Giant Eagle Pharmacy #4098, in Chardon, Ohio, “from May 1, 2009, through January 21, 2011, fail[ed] to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs, to wit: the following controlled substances and dangerous drugs were stolen from the pharmacy yet internal control procedures failed to deter or detect the theft. The drugs were stolen

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<sup>19</sup> See PSJ13-HBC Exh 1, Interrog. No. 23, p. 42 (HBC provided no “educational, information and/or other programs to any Customer and/or pharmacy/dispenser that it owns and/or controls or other Person, that address diversion, safety, efficacy, misuse and/or prescription of Schedule II Opioids.” (“[O]ther Person” would include warehouse personnel and other employees)).

<sup>20</sup> See Chunderlik Dep., Dkt. # 1959-24 at 134:8-13, 217:21-218:19, 305:4-14; Carlson Dep., Dkt. # 1959-18 at 208:1-11; Tsipakis Dep., Dkt. # 1971-12 at 60:16-161:4.

<sup>21</sup> Thomas Prevoznik Dep. (May 17, 2019), Dkt. # 1969-14 at 913:23-914:11.

<sup>22</sup> Carlson Dep., Dkt. # 1959-18 at 102:22-103:13; Anthony Mollica Dep. (Jan. 4, 2019), Dkt. # 1968-5 at 89:23-95:16.

by an inadequately supervised technician who admitted to a Board agent that the drugs were diverted to her addicted husband and also sold to another individual.”<sup>23</sup>

<b>TABLE FROM OHIO BOARD OF PHARMACY DOCKET NUMBER D-110714-197: IN THE MATTER OF GIANT EAGLE PHARMACY #4098</b>			
<b>Drug</b>	<b>Strength</b>	<b>Shortage<sup>24</sup></b>	<b>Percent of stock<sup>25</sup></b>
hydrocodone with APAP <sup>26</sup>	5/325	1,321	53.92
hydrocodone with APAP	5/500	(-648)	0.65
hydrocodone with APAP	7.5/325	5,237	67.49
hydrocodone with APAP	7.5/500	6,161	72.06
hydrocodone with APAP	7.5/750	30,566	57.67
hydrocodone with APAP	10/325	5,282	75.67
hydrocodone with APAP	10/500	14,586	75.19
hydrocodone with APAP	10/650	5,523	82.07
hydrocodone with APAP	10/660	17,512	82.22
hydrocodone with ibuprofen <sup>27</sup>	7.5/200	1,057	52.33
carisoprodol <sup>28</sup>	350	7,556	27.68
Suboxone <sup>29</sup>	8	553	20.04

These figures demonstrate HBC’s failure to prevent diversion and its knowledge of that diversion.

#### 4. *Giant Eagle’s Pharmacists Did Not Prevent Diversion*

The State of Ohio Board of Pharmacies found Giant Eagle Pharmacist Douglas E. Urbaniak liable for failing to prevent diversion which occurred under his supervision, in violation of Ohio Administrative Rule 4729-9-11.<sup>30</sup> Additional unreported diversion is evidenced in monthly narcotic

<sup>23</sup> PSJ13-HBC Exh 10, OHIOPHARM000000063 at .0003-.0006, State of Ohio Board of Pharmacy Mins., Dec. 5-7, 2011 “Settlement Agreement with the State Board of Pharmacy, *In the Matter of Giant Eagle #4098*, Docket Number D-110714-197; *see also* Mollica Dep., Dkt. # 1968-5 at 89:23-95:16.

<sup>24</sup> “Shortage” is the amount that the Ohio Board of Pharmacy found was missing for a particular strength (negative numbers would be an excess for that strength).

<sup>25</sup> “Percent of stock” is the amount of stock of Giant Eagle Pharmacy 4098 that was missing for a particular strength, expressed as a percent.

<sup>26</sup> “Hydrocodone with APAP” is the drug sometimes branded as “Vicodin.” Total missing here is 86,188 units.

<sup>27</sup> “Hydrocodone with ibuprofen” is a similar drug. Total missing here is 1,057 units.

<sup>28</sup> Carisoprodol is a Schedule IV drug.

<sup>29</sup> Suboxone is a Schedule III drug.

<sup>30</sup> *See* PSJ13-HBC Exh 10 at .0007-.0010.

audit reports and Giant Eagle Pharmacy District Leader Fred Bencivengo testified as to several instances in a single narcotic audit report where suspected diversion of HCPs should have been reported.<sup>31</sup>

**B. HBC DISTRIBUTED MILLIONS OF DOSAGE UNITS INTO CUYAHOGA AND SUMMIT COUNTIES**

Before implementing its first threshold report on October 15, 2013, HBC shipped nearly 20 million units of HCP into Summit and Cuyahoga Counties with no monitoring and with no identified SOM policy:

<b>Jurisdiction</b>	<b>Units Shipped (11/12/2009–10/14/2013)</b>
Cuyahoga County	10,684,835 <sup>32</sup>
Summit County	8,700,931 <sup>33</sup>

After its threshold program was finally implemented on October 15, 2013, HBC shipped the following amounts of HCPs into Summit and Cuyahoga Counties:

<b>Jurisdiction</b>	<b>Units Shipped (10/15/2013–9/30/2014)</b>
Cuyahoga County	1,940,344 <sup>34</sup>
Summit County	1,822,912 <sup>35</sup>

**II. ARGUMENT**

**A. PLAINTIFFS HAVE ESTABLISHED THEIR NEGLIGENCE CLAIM**

*1. Plaintiffs Have Rebutted HBC's Expert Evidence*

Plaintiffs have set forth a standard of care applicable to HBC and other distributors of controlled substances, and have submitted reports from two experts who both detail the standard of care applicable for all distributors, as well as testimony from numerous witnesses, including highly placed individuals at the DEA (Thomas Prevoznik and Joseph Rannazzisi). These standards apply to

<sup>31</sup> Fred Bencivengo Dep. (Jan. 22, 2019), Dkt. # 1959-1 at 120:21-121:8, 123:25-125:13, 135:23-136:9, 137:1-9, 139:7-23, 142:13-143:9.

<sup>32</sup> PSJ13-HBC Exh 2.

<sup>33</sup> PSJ13-HBC Exh 3.

<sup>34</sup> PSJ13-HBC Exh 2.

<sup>35</sup> PSJ13-HBC Exh 3.

all Distributor Defendants who chose to engage in the distribution of controlled substances, including HBC. *See generally* Mem. in Supp. of Pls.’ Mot. For Partial Summ. Adjudication of Defs.’ Duties Under the Controlled Substances Act, Dkt. # 1887.

In response, HBC argues that Plaintiffs’ negligence claim must be dismissed because they “‘must present expert testimony in order to establish that Defendants breached any such standard of care found in the regulations.’” HBC Mem. 10 (quoting *Kinn v. HCR Manorcare*, 2011 Ohio Misc. LEXIS 13507, at \*5 (Ohio Ct. Com. Pl. Nov. 29, 2011)). Contrary to HBC’s arguments, expert testimony is not required when, as here, negligence is recognizable to the layman.<sup>36</sup> *See, e.g., Frey v. Sun Oil Co.*, 2018 WL 6258907, at \*2 (Pa. Super. Ct. Nov. 30, 2018) (“[W]e agree with Frey’s argument that expert testimony of industry custom or standard is not required where the facts are not complicated and the danger is apparent from the act itself.”); *Oliver v. Amity Mut. Irrigation Co.*, 994 P.2d 495, 497 (Colo. App. 1999) (“Colorado courts have declined to require expert testimony in similar circumstances involving allegations of noncompliance with industry standards.”); *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 210 (Colo. 1984) (noting “question whether [defendant] breached the standard of care applicable to a reasonable pharmaceutical company does not entail specialized knowledge” beyond “the ken of persons of ordinary intelligence” and, thus, did not require expert testimony).

Indeed, HBC’s own case law makes clear that this also is the rule in Ohio. HBC cites to *Skiles v. Bellevue Development Corp.*, 2008-Ohio-78, 2008 WL 110628 (Ct. App. Jan. 11, 2008), *see* HBC Mem. 13, but *Skiles*, itself, cites to the Ohio Supreme Court’s holding that “[e]xpert-opinion evidence is not required or necessary where the subject of the inquiry is within the common, ordinary and general experience and knowledge of mankind, but such evidence is required where the inquiry pertains to a highly technical question of science or art or to a particular professional or mechanical

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<sup>36</sup> In *Kinn*, the court found that “*for purposes of argument only*,” the plaintiff must present expert testimony in a case when there was “no testimony stating that Defendants violated Ohio law with their actions.” 2011 Ohio Misc. LEXIS 13507, at \*5-6. *Kinn* is thus readily distinguishable.

skill,” *id.* at ¶ 32 (quoting *Jones v. Hawkes Hosp. of Mt. Carmel*, 175 Ohio St. 503, 503, 196 N.E.2d 592, 593 (1964)).

This is precisely the case here, where the jury will be asked to determine straightforward issues such as whether HBC had suspicious ordering monitoring programs that met the requirements of the CSA and whether HBC complied with its obligations under the CSA. Moreover, the jury will receive the benefit of expert testimony, including Plaintiffs’ experts, James Rafalski and Dr. Seth Whitelaw. Put simply, while not required, Plaintiffs do have expert testimony that establishes the standard of care for their negligence claims, and the jury will easily be able to determine whether HBC breached this standard even without it.

## 2. *Plaintiffs Have Demonstrated Injury and Proximate Harm*

Giant Eagle argues that it did not cause injury because, in Plaintiffs’ interrogatory responses, of the 124 prescriptions filled by Giant Eagle pharmacies none “was a product that Giant Eagle distributed.” *See* HBC Mem. 14-15. These arguments are unavailing. In the discovery ruling relied upon by HBC, the Special Master simply ordered that Plaintiffs identify ten prescriptions that were sold by each manufacturing defendant. The Special Master did not require Plaintiffs to identify any suspicious prescriptions distributed by any distributor defendants. *See* Discovery Ruling No. 5, ECF No. 1027, at 2, 4, 5 (“Plaintiffs’ responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant.”). That the limited number of prescriptions identified in certain interrogatory responses were not distributed by Giant Eagle is simply irrelevant. Notwithstanding, publicly available information shows that prescriptions filled by Giant Eagle pharmacies were diverted. *See United States v. Eppinger*, 2012 WL 6930580, at ¶¶ 114, 116, 119 (N.D. Ohio Mar. 13, 2012) (listing fraudulent prescriptions filled at Giant Eagle pharmacies in Garfield Heights, Ohio).

Second, as described in Plaintiffs’ Plaintiffs’ Consolidated Memorandum in Opposition to Defendants’ Motions for Summary Judgment on Proof of Causation, which is incorporated by

reference herein, Plaintiffs are entitled to prove their claims by aggregate proof without the need to identify specific inappropriate prescriptions.

Finally, when, as here, a plaintiff suffers an injury of the sort that is expected from a defendant's misconduct, causation is presumed. *See generally* Pls.' Consolidated Mem. in Opp'n to Defs.' Mots. for Summ. J. on Proof of Causation.

**B. PLAINTIFFS HAVE PUT FORWARD EVIDENCE TO SUPPORT THEIR REMAINING CLAIMS**

HBC argues that Plaintiffs' remaining claims for public nuisance, injury through criminal acts, unjust enrichment, and punitive damages fail. *See* HBC Mem. 15-18. These arguments are unavailing because, as demonstrated in Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them ("CSA - Compliance"), Dkt. # 1924, Plaintiffs have shown that HBC not only engaged in wrongdoing sufficient to satisfy these claims, but that the evidence is so overwhelming that Plaintiffs are entitled to summary judgment in their favor, *see id.* at 132-39.

Notwithstanding, HBC argues that Plaintiffs' public nuisance claim must fail because it "moved relatively modest amounts of medication from a Giant Eagle warehouse to Giant Eagle pharmacies, where licensed pharmacists dispensed them pursuant to legitimate prescriptions." HBC Mem. 15-16. HBC neglects to mention that these "modest amounts" represented more than 23 million units of HCPs, which is more than sufficient to allow for a finding of public nuisance. *See generally* Mot. of Pls. Cuyahoga & Summit Ctys. for Partial Summ. Adjudication of Their Equitable Claims for Abatement of an Absolute Public Nuisance. HBC's attempts to downplay its role in causing Plaintiffs' injuries should be rejected.

The fact that "both the State of Ohio and the DEA licensed, inspected, and audited Giant Eagle's distribution activities and order monitoring procedures," HBC Mem. 16, does not provide a

bar to Plaintiffs' claims because Plaintiffs are not seeking to hold HBC liable under a theory of strict liability, but rather for negligent and intentional misconduct. Neither the State of Ohio nor the DEA ever specifically approved Giant Eagle's suspicious ordering monitoring policies, and such license, inspection, and audit did not give Giant Eagle a free pass to fail to comply with the CSA.

With respect to Plaintiffs' allegations regarding criminal misconduct, the evidence shows that HBC violated Ohio R.C. § 2925.02 by deliberately disregarding its obligations to maintain effective controls against diversion. *See* CSA - Compliance 132-39. In response, HBC argues that "[t]here is zero evidence that Giant Eagle corrupted anyone with drugs, intended to cause physical harm to anyone, or distributed medication that was wrongfully diverted." HBC Mem. 17. The plain language of the statute makes clear that this is not the standard. *See* Ohio Rev. Code § 2925.02(A) ("No person shall knowingly do any of the following: . . . (2) By any means, administer or furnish to another or induce or cause another to use a controlled substance with purpose to cause serious physical harm to the other person, or with purpose to cause the other person to become drug dependent; (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."); *see also In re Nat'l Prescription Opiate Litig.*, 2018 WL 4895856, at \*34 (N.D. Ohio Oct. 5, 2018) (upholding Plaintiffs' claims for injuries through criminal acts).

### III. CONCLUSION

For the foregoing reasons and those in Plaintiffs' memoranda of law cited herein, the Court should deny HBC's motion for summary judgment.

Dated: July 31, 2019

Respectfully submitted,

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